

NIH human embryonic stem cell guidelines responsive to comments from the research community

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San Francisco, Calif., July 6, 2009 – CIRM is encouraged by the NIH human embryonic stem cell research guidelines announced today, which take into account extensive input from research organizations, scientists and patients. The process for evaluating eligible lines and the registry of approved human embryonic stem cell lines to be developed by the NIH represents an enormous step forward. The final guidelines will ease barriers that have slowed responsible embryonic stem cell research in the United States and with international partners.

The new guidelines, which are consistent with CIRM governing board recommendations on the draft guidelines, create a framework for evaluating human embryonic stem cell lines created before July 7, 2009. The framework is in line with criteria developed by the National Academies of Sciences (NAS), which also serves as the basis for CIRM's policy governing acceptable cell lines.

Under the new guidelines, the NIH will determine which lines conform to fundamental eligibility criteria and have donors that provided voluntary informed consent. These lines will then become part of a registry and be eligible for NIH funding. Changes from the draft guidelines reflect input from CIRM's Governing Board task force and input from other national and international groups concerned about fostering scientific partnerships.

Alan Trounson, CIRM president, said these guidelines are an important step forward for the type of international partnerships that the organization has been encouraging. "The NIH showed foresight by specifically laying out a procedure for how lines derived outside the United States may be included in the registry. The revised policy recognizes the global aspect of stem cell science and supports existing international collaborations."

By adopting an approach consistent with the recommendations of the National Academies of Sciences, the NIH guidelines are consistent with those of the international research community. California and other states committed to advancing regenerative medicine. Having a consistent national policy on stem cell research is a significant move toward ethically responsible and scientifically worthy research. These guidelines also protect those who donated embryos leftover from in vitro fertilization in order to advance this promising field of research.

"These guidelines will enable California stem cell scientists to work more effectively with their colleagues in other states or around the world to bring new treatments to the people of California," said Robert Klein, chair of the Governing Board. "With a registry of cell lines available for NIH funding, California scientists and their colleagues outside the state can benefit from CIRM and NIH funding while working with the best embryonic stem cell lines. We can expect the pace of discovery to move even faster toward new cures for patients."

The NIH has committed to periodically re-evaluate the scope of these guidelines in light of medical and scientific advances. CIRM looks forward to working with the NIH to evaluate the inclusion of parthenogenesis and SCNT lines in the future. As the Governing Board put forward in their recommendations, CIRM views all sources of hESCs – including somatic cell nuclear transfer and parthenogenesis – as potentially important for advancing regenerative medicine. The organization will continue to uphold the highest standards of oversight for hESC derivation and research not currently eligible for federal funding. This commitment will enable NIH to leverage current efforts in its future programs.

About CIRM CIRM was established in November, 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research opportunities. To date, the CIRM governing board has approved 295 research and facility grants totaling more than \$761 million, making CIRM the largest source of funding for human embryonic stem cell research in the world. For more information, please visit www.cirm.ca.gov.

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